Minutes of the expert groups

Meeting of the Medical Device Coordination Group - Subgroup on Standards (Working Group 2)[1]

28 January 2022

Nature of the meeting

The meetings of the Medical Device Coordination Group (MDCG) and its subgroups are not public and intended only for MDCG members and observers, chaired by the relevant Commission services (COM) in the field of medical devices[2].

This was the fourth meeting of the MDCG Subgroup on Standards (Working Group 2), after the first one on 20 May 2019[3], the second one on 19 June 2020[4] and the third one on 7 June 2021[5]. Due to the COVID-19 pandemic, the meeting was held by remote with audio-video connection via WebEx, as timely communicated to all the registered participants.

The minutes of the previous meeting held on 7 June 2021 were approved by written procedure in CIRCABC on 13 September 2021.

1. Opening, adoption of the agenda

The agenda of the meeting was approved without any change.

2. Standardisation for medical devices: state of play and perspectives

2.1. Development and assessment of harmonised standards in support of the MDR and the IVDR

COM informed on the ongoing activities, in particular on:
- the development of harmonised standards by CEN-CENELEC and their Technical Committees on the basis of the standardisation request issued by COM;
- the assessment by COM, with the support of the HAS consultants, of draft harmonised standards suitable to be cited in the *Official Journal of the European Union* (OJEU) under

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565: https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=3565.
[2] Directorate-General for Health and Food Safety (DG SANTE), Unit B.6 - Medical Devices, Health Technology Assessment. Commission's sectorial website on medical devices: https://ec.europa.eu/health/medical-devices-sector_en; contact: SANTE-MED-DEV@ec.europa.eu.
[3] https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=17334&fromExpertGroups=true.
[4] https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=21190&fromExpertGroups=true.
[5] https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=25914&fromExpertGroups=true.

the Medical Devices Regulation (EU) 2017/745 (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) to confer presumption of conformity with the requirements of the Regulations the standards aim to cover;
- the continuous cooperation and dialogue between COM, the CEN-CENELEC Management Centre (CCMC) and the Technical Committees on relevant issues on harmonised standards, to solve problems on the basis of cooperative and pragmatic approaches;
- the CEN-CENELEC Advisory Board on Healthcare Standards (ABHS) as a forum for extended dialogue with the standardisation experts, referring to their latest meetings held in June and October 2021, and to the next meeting planned to take place in June 2022;
- the reinforcement of the HAS consultants team, with currently 7 experts with higher degrees of expertise and flexibility, to effectively address the needs for assessment of draft harmonised standards.

The attendees generally appreciated the report and raised no questions.

2.2. Publications in the OJEU of references of harmonised standards in support of the MDR and the IVDR

COM informed on the first publications that took place in July 2021[6] and in January 2022[7], reaching overall 14 references for the MDR and 9 references for the IVDR. Consolidated versions of the lists are also available in .pdf and .xls formats on the standardisation pages for medical devices[8] and *in vitro* diagnostic medical devices[9]. New publications as amendments of the first publications will continue to take place regularly, to enlarge the lists according to the development of the standardisation work at European and international level, as provided by CEN-CENELEC. The next publications are currently under preparation, to take place likely in March/April 2022.

The attendees generally appreciated the possibility of counting on more harmonised standards for the Regulations, especially the more significant ones as for quality management systems (EN ISO 13485) and for symbols (EN ISO 15223-1), and asked for which new harmonised standards are going to be published and the timing, especially for risk management (EN ISO 14971). COM mentioned the standards proposed by CEN-CENELEC in January 2022 and

[6] Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L 256, 19.7.2021, p. 100) https://eur-lex.europa.eu/eli/dec_impl/2021/1182/oj, and Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for in vitro diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 258, 20.7.2021, p. 50) https://eur-lex.europa.eu/eli/dec_impl/2021/1195/oj.

[7] Commission Implementing Decision (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment (OJ L 1, 5.1.2022, p. 11) https://eur-lex.europa.eu/eli/dec_impl/2022/6/oj, and Commission Implementing Decision (EU) 2022/15 of 6 January 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer and requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (OJ L 4, 7.1.2022, p. 16) https://eur-lex.europa.eu/eli/dec_impl/2022/15/oj.

[8] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en.

[9] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en.

confirmed that more detailed information will be shared as soon as available. In particular, the draft new Implementing Decisions amending and enlarging the previous ones will be circulated in CIRCABC before launching the formal procedure for adoption.

Some attendees asked for the possibility to have a programme/prioritisation document for the development of harmonised standards, more detailed than the standardisation request and the CEN-CENELEC joint work programme, in order to be aware on which standards would be proposed for harmonisation and publication in the OJEU during the time. COM and CEN-CENELEC referred to the publicly available database on standards[10] but in any case they will check how to improve the current communication system. More information in case of specific needs may be always requested directly by e-mail.

2.3. Draft amendment to the standardisation request

COM recalled the contents of the standardisation request in support of the MDR and IVDR[11] and presented a draft amendment with the list of standardisation items to be added and to be removed in Annexes I and II, under preparation on the basis of inputs and discussions with CEN-CENELEC.

Some attendees asked for more information on the reasoning for adding or removing some items. COM and CEN-CENELEC explained some cases, but more detailed information will be included in the draft amendment itself, to be circulated in CIRCABC before launching the formal procedure for possible adoption by Q2/2022. COM recalled that such a procedure is governed by the horizontal Regulation (EU) No 1025/2012 on European standardisation, including the opinion of the Committee on Standards: in this sense, COM invited the members and observers of the Subgroup to liaise with their representatives in that Committee to ensure coherent and effective communication.

3. Reports on the activities of the task forces

3.1. TF#1 "Standardisation guidance"

COM reported on the task force on "Standardisation guidance" (TF#1), aiming at developing guidance documents on standardisation issues for medical devices, for the possible revision and improvement of the first one published in April 2021[12], and exploring the possibility for developing other specific guidance documents. It was launched in September 2021 with 11 members and observers of the Subgroup from Member States, notified bodies, industry, authorised representatives. A first meeting was held in October 2021, agreeing to work on the update and further development of the first general guidance document in terms of two main priorities: "state of the art" and "court cases". Written proposals and contributions would be integrated in a first revised draft, to be discussed at next meetings of the TF#1 in February or March 2022. The work was paused for other urgencies but is to be retaken soon, hopefully to

[10] CEN - CENELEC - Search standards: https://standards.cencenelec.eu/.

[11] Commission Implementing Decision of 14.4.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (C(2021) 2406) https://ec.europa.eu/health/system/files/2021-04/c_2021_2406_annex_en_0.pdf.

[12] MDCG 2021-5 Guidance on standardisation for medical devices https://ec.europa.eu/health/system/files/2021-04/md_mdcg_2021_5_en_0.pdf.

submit an advanced draft to the consideration of all the members and observers at the next meeting of the Subgroup in June 2022.

3.2. TF#2 "'Cookbook' for standards"

COM and CLC/TC 62 reported on the task force on "'Cookbook' for standards" (TF#2), that was set up to discuss the proposal by CLC/TC 62 of a practical tool for the development of harmonised standards for electrical medical equipment and possible extension to other types of standards for medical devices. It was launched in September 2021 with 13 members and observers of the Subgroup from Member States, notified bodies, standardisation, industry, authorised representatives. Three meetings were held so far between September 2021 and January 2022, resulting in a revised and improved version of the text, taking into account comments and contributions by the members of the TF#2, COM and CLC/TC 62 experts. The current clean version was submitted at the meeting of the Subgroup for the consideration and comments by the members and observers, to be summarised in a new meeting of the TF#2 in February 2022. The final draft will be circulated afterwards for the approval of the MDCG Standards Subgroup. It is not intended to become a MDCG-endorsed guidance document, but an internal tool for CEN-CENELEC and their Technical Committees, recognised as useful.

Some attendees asked for more clarification on the contents and use of the document, in particular to ensure that it will remain within the legislative and procedural framework for standardisation for medical devices, and at the same time helping to produce harmonised European standards in sound relationship with international standards, clearly defining which legal requirements are covered to confer presumption of conformity, and those which not. The work of the ESOs to develop harmonised European standards based on international standards should not be limited to a table of correspondence and to indicate which EU regulatory requirements are not taken into account in an international standard: harmonised standards should cover a maximum of EU regulatory requirements. COM and CLC/TC 62 addressed the questions providing reassurance on the positive role and usefulness of the document, also clarifying that the ongoing discussion on it would not block the standardisation work to be carried out in TC 62 as well as in others TCs.

COM asked for written comments, contributions and suggestions by the members and observers of the Subgroup in two-week time, until 11 February 2022, to be taken into account by the members of the TF#2 ahead of their next meeting in the third week of February. On that basis, further improvements will take place on the text, to produce a revised final version to be circulated in CIRCABC and submitted to the consideration and approval at the next meeting of the Subgroup in June 2022.

4. Draft Work Programme 2022

COM presented the draft work programme for 2022 of the MDCG Subgroup on Standards, very much based on the 2021 edition with the necessary adjustments on the three priorities: updates of the standardisation request, publication in the OJEU of references of harmonised standards, development of guidance documents and other documents. The draft was circulated in CIRCABC on 13 January 2022 for written consideration, to be discussed and approved at the meeting of the Subgroup on 28 January, then to be submitted to the MDCG for endorsement. It is organised by work packages and tasks with different timelines and priorities, substantially in continuity with the Work Programme 2021:

- Standardisation requests: Commission Implementing Decisions periodically amending the MDR/IVDR standardisation request
- Harmonised standards: publications in the OJEU of lists of references of harmonised standards in support of the Regulations, amending and enlarging those published in July 2021
- Guidance and other documents: revision of the MDCG Guidance on standardisation for medical devices, and 'Cookbook' for standards

All the items consider the active participation of competent authorities (CA) members, stakeholders and other interested parties.

After some discussion, the draft work programme for 2022 was approved by the members of the Subgroup with two formal changes:
- in items 1/1/1 and 2/1/1, in the column "Link to other WGs", instead of "n/a" (not applicable), insert "tbd" (to be defined), to open the possibility to involve also other working groups in the activities related to the standardisation request and the publication of harmonised standards, for instance those for notified bodies (NBO), IVD, international etc.;
- in item 3/2/1, change the timeline to Q2/2022 instead of Q1/2022 for the "Cookbook", considering that not only the work of the TF#2 should be considered by the end of March, but also the subsequent discussion and submission to the consideration and approval of the Subgroup at the meeting in June.

The approved version of the work programme 2022 will be recirculated in CIRCABC, then transmitted to the MDCG for consideration and endorsement at their meeting in March, alongside the work programmes of the other 12 Subgroups.

5. European and international standardisation: horizontal ongoing activities

COM informed on several horizontal ongoing activities in European and international standardisation:
- The upcoming adoption of the EU Standardisation Strategy, within the updated "New Industrial Strategy"[13], as part of a "Standardisation package" that includes a Commission Communication "An EU Strategy on Standardisation in support of international leadership and a resilient, green and digital EU Single Market", a Report on the implementation of Regulation (EU) No 1025/2012 on European standardisation, the Annual Union work programme for European standardisation for 2022, and a Proposal to amend Regulation (EU) No 1025/2012 on European standardisation
- The final steps towards the adoption of a revised "The 'Blue Guide' on the implementation of EU product rules", including the contents on standardisation
- The internal and external dialogues and discussions on standardisation, including the Brainstorming group ISO-IEC-CEN-CENELEC-COM to address cases of negative assessments and agree on solutions; the Joint Task Force ESOs-COM on timely delivery and citation in the OJEU of harmonised standards; the COM inter-service group on standardisation; the international dialogues with the USA (TTC WG 1 TSC) and other countries; etc.

[13] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery (5.5.2021, COM(2021) 350) https://ec.europa.eu/info/sites/default/files/communication-industrial-strategy-update-2020_en.pdf.

The attendees generally appreciated the report and raised no questions. COM will provide through CIRCABC the references of the documents to be adopted within the "Standardisation package" and other relevant documents from other initiatives as soon as they are available.

6. AOB

The European Biosafety Network (EBN) reported on the development of the international standard on sharp injury protection (ISO/AWI 23908), informing on the initiative for a (hybrid?) workshop on the issue in June 2022. COM appreciated the initiative and invited the attendees, in particular CEN, to liaise with EBN to contribute as appropriate.

7. Next meeting

The second 2022 annual plenary meeting (members and observers) of the MDCG Standards Subgroup is planned to take place on 8 June. Meetings in 2023 are tentatively scheduled in January/February, and in June.

COM will define and confirm timing and modalities of these meetings as soon as possible.

List of participants

Members - National competent authorities:
Belgium (BE), Czech Republic (CZ), Germany (DE), Estonia (EE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Portugal (PT), Romania (RO), Slovenia (SL), Slovakia (SK), Finland (FI), Sweden (SE)

Observers - National competent authorities:
Turkey (TK)

Observers - Stakeholders' organisations:
Association of the European Self-Medication Industry (AESGP), APPLiA (Home Appliance Europe), Biomedical Alliance in Europe (BioMed Alliance), European Committee for Standardization (CEN) – European Committee for Electrotechnical Standardization (CENELEC), European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), European Association of Authorised Representatives (EAAR), European Association of the Contact Lens and Lens Care Products Manufacturers (EUROMCONTACT), European Biosafety Network (EBN), European Council of Optometry and Optics (ECOO) – EurOptom, European Society of Cardiology (ESC), Federation of the European Dental Industry (FIDE), MedTech Europe (MTE), Notified Bodies Coordination Group Medical Devices (NBCG-Med), European Association for Medical Devices of Notified Bodies (Team-NB)

European Commission:
SANTE B.6
HAS consultants